K121682 (1/3)

OCT 4 2012

510(k) SUMMARY

Intelligent Implant Systems's ACTIVE™ Screw Bone Screw

Company Name:	Intelligent Implant Systems, LLC 3300 International Airport Drive, Suite 1100 Charlotte, NC 28208 (704) 424-1009 (704) 424-1011 (fax)
510(k) Contact:	Michael Nutt Chief Operations Officer (704) 424-1009
Date Prepared:	August 30, 2012
Proprietary Name:	**ACTIVE™ Screw Bone Screw**
Common Name:	Bone Screw
Classification:	21 CFR 888.3040 - Class II
Device Product Code:	HWC: Screw, Fixation Bone 87 Orthopedics
Predicate Devices:	K961157 - Whiteside Biomechanics Cancellous Bone Screw, K102429, K112772 - Wright Medical Technology ORTHOLOC™ Bone Screws, K061621 – Synthes (USA) 6.5 mm Cancellous Screws

Device Description:

The ACTIVE ™ Screw Bone Screws subjected to this premarket notification are 4.5 mm diameter screws available in 5 mm length increments from 20 to 50 mm. The screws are manufactured from titanium alloy and have an expandable thread crest. The implants are single use only devices.

Intended Use / Indications for Use

The ACTIVE ™ Screw Bone Screw is intended for implantation into prepared bone during orthopaedic surgery when the surgeon determines the need for additional fixation: bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

The ACTIVE™ Screw Bone Screw is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Technological Characteristics

The ACTIVE ™ Screw Bone Screw consists of a screw shank in conjunction with a spiral helical thread crest component. With the spiral helical thread component, the screw has the ability to expand an additional 1 mm after implantation.

The ACTIVE ™ Screw Bone Screw is made of wrought titanium 6Al-4V ELI (ASTM F136) and is available in a 4.5 mm diameter size from 20 mm to 50 mm and will be provided non-sterile, and is to be steam sterilized by the end user. Resterilization of screws upon contamination is not recommended.

Performance Data

Torsion testing was conducted according to the standard bone screw testing method (Method A1 in ASTM F543-07) and the torsional strength and breaking angle exceeded the minimum required values for comparable screws of the same size. In addition, axial pullout strength testing and torque in/ torque out testing were conducted on the ACTIVE™ Screw Bone Screw and the results were acceptable.

Additional evaluation and testing was undertaken to determine the forces exerted on the bone after implantation of the helical thread crest component and the damage that the removal of the thread crest component may inflict on the surrounding bone. The forces were found to be physiologically safe to the bone and the damage generated by the removal of the thread crest component did not exceed damage resulting from the removal of a traditional (predicate) bone screw.

In all instances, the ACTIVE™ Screw Bone Screw functioned as intended and the testing results observed were acceptable.

Substantial Equivalence

The ACTIVE ™ Screw Bone Screw is substantially equivalent in design and function to the bone screws marketed by Wright Medical Technology (K102429, K112772), Whiteside Biomechanics (K961157), and Synthes (USA) (K061621). Like the predicate devices, the subject screw is composed of titanium alloy and is used in the same applications where the surgeon determines the need for additional fixation.

Substantial equivalence is shown through mechanical testing, materials information, and comparison of design characteristics. The results show that the subject ACTIVE™ Screw Bone Screw can be expected to perform at least as well as the legally marketed predicate ORTHOLOC™ Bone screws, Whiteside Biomechanics Bone Screws, and Synthes (USA) Cancellous Screws

The performance data demonstrate the ACTIVE ™ Screw Bone Screw is as safe and effective as the predicate devices. The ACTIVE ™ Screw Bone Screw has the same or similar intended uses and indications, technological characteristics, and principles of operation as its predicate devices. The differences between the ACTIVE ™ Screw Bone Screw and its predicate devices raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 4 2012

Intelligent Implant Systems, LLC
% Mr. Michael J. Nutt
Chief Operating Officer
3300 International Airport Drive, Suite 100
Charlotte, North Carolina 28208

Re: K121682
Trade/Device Name: Active Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 30, 2012
Received: August 31, 2012

Dear Mr. Nutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

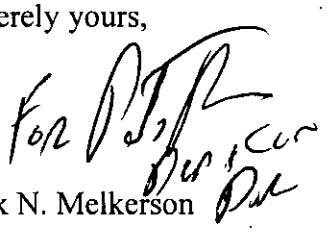
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121682

Device Name: ACTIVE™ Screw Bone Screw

Intended Use:

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121682